## Food and Drug Administration, HHS

(3) Limitations. Do not use in dogs with cardiac disease, respiratory disorders, liver or kidney diseases, dogs in shock, dogs which are severly debilitated, or dogs which are stressed due to extreme heat, cold, or fatigue. Allow agitated dogs to rest quietly before administration. Do not repeat dosing in dogs not responding satisfactorily to treatment. Do not use in breeding or pregnant animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[61 FR 21075, May 9, 1996]

## §522.1350 Melatonin implant.

- (a) *Specifications*. The drug is a silicone rubber elastomer implant containing 2.7 milligrams of melatonin.
- (b) Sponsor. See No. 053923 in \$510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. One implant per mink.
- (2) *Indications for use.* For use in healthy male and female kit and adult female mink (*Mustela vison*) to accelerate the fur priming cycle.
- (3) *Limitations*. For subcutaneous implantation in mink only. Do not implant potential breeding stock. Do not use in food-producing animals.

[59 FR 37422, July 22, 1994]

## § 522.1362 Melarsomine dihydrochloride for injection.

- (a) Specifications. The drug consists of a vial of lyophilized powder containing 50 milligrams of melarsomine dihydrochloride which is reconstituted with the provided 2 milliliters of sterile water for injection.
- (b) Sponsor. See No. 050604 in §510.600(c) of this chapter.
- (c) Conditions of use—(1) Amount. For asymptomatic to moderate (class 1 to class 2) heartworm disease: 2.5 milligrams per kilogram of body weight (1.1 milligram per pound) twice, 24 hours apart. The series can be repeated in 4 months depending on the response to the first treatment and the condition, age, and use of the dog. For severe (class 3) heartworm disease: Single injection of 2.5 milligrams per kilogram followed, approximately 1 month later, by 2.5 milligrams per kilogram administered twice, 24 hours apart.

- (2) Indications. Treatment of stabilized, class 1, 2, and 3 heartworm disease (asymptomatic to mild, moderate, and severe, respectively) caused by immature (4 month-old, stage L<sub>5</sub>) to mature adult infections of Dirofilaria immitis in dogs.
- (3) Limitations. Administer only by deep intramuscular injection in the lumbar muscles ( $L_3$ - $L_5$ ). Use a 23 gauge 1 inch needle for dogs less than or equal to 10 kilograms (22 pounds) and a 22 gauge 1 1/2 inch needle for dogs greater than 10 kilograms (22 pounds). Use alternate sides with each administration. The drug is contraindicated in dogs with class 4 (very severe) heartworm disease (Caval Sydrome). Not for use in breeding animals and lactating or pregnant bitches. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[60 FR 49340, Sept. 25, 1995]

## §522.1367 Meloxicam.

- (a) Specifications. Each milliliter of solution contains 5.0 milligrams (mg) meloxicam.
- (b) Sponsor. See No. 000010 in \$510.600(c) of this chapter.
- (c) Conditions of use—(1) Dogs—(i) Amount. Administer 0.09 mg per pound (mg/lb) body weight (0.2 mg per kilogram (mg/kg)) by intravenous or subcutaneous injection on the first day of treatment. For treatment after day 1, administer meloxicam suspension orally at 0.045 mg/lb (0.1 mg/kg) body weight once daily as in §520.1350(c) of this chapter.
- (ii) *Indications for use*. For the control of pain and inflammation associated with osteoarthritis.
- (iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.
- (2) Cats—(i) Amount. Administer 0.14 mg/lb (0.3 mg/kg) body weight as a single, one-time subcutaneous injection.
- (ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration when administered prior to surgery.